MORRIS, NICHOLS, ARSHT & TUNNELL LLP

1201 NORTH MARKET STREET
P.O. BOX 1347
WILMINGTON, DELAWARE 19899-1347

(302) 658-9200
(302) 658-3989 FAX

KAREN JACOBS LOUDEN
(302) 351-9227
(302) 425-4681 FAX
klouden@mnat.com

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BY E-FILING AND FAX

The Honorable Joel Schneider
United States District Court
for the District of New Jersey
Mitchell H. Cohen Building
4th & Cooper Streets, Room 1050
Camden, NJ 08101

Re: ***Sciele Pharma, Inc. v. Lupin Ltd., et al.*****, C.A. No. 09-037 (RBK) (JS)**
Shionogi Pharma, Inc. v. Mylan Inc., et al.**, C.A. No. 10-135 (RBK) (JS)**
(Consolidated)

Dear Magistrate Judge Schneider:

Pursuant to the December 16, 2011 Amended Scheduling Order (D.I. 292), Plaintiff Sciele Pharma, Inc., n/k/a Shionogi Inc. ("Shionogi") submits this letter outlining outstanding discovery disputes between Shionogi and Defendants Lupin Ltd. and Lupin Pharmaceuticals, Inc. ("Lupin") and Mylan Inc. and Mylan Pharmaceuticals, Inc. ("Mylan") in advance of the April 5, 2012 status conference.

Shionogi, together with co-Plaintiff Andrx Corp. ("Andrx"), met and conferred with Lupin and Mylan in an attempt to resolve discovery disputes. While Plaintiffs believe that some disputes were resolved, the following disputes (discussed in more detail below) require the Court's attention:

1. Lupin's refusal to provide damages-related discovery;

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2. Lupin's deficient responses to various other document requests;

3. Mylan's deficient responses to Interrogatories asking Mylan to identify persons; and

4. Disputes concerning the location of depositions and depositions of Chief Executive Officers.

In addition, the parties all agree that the current schedule for fact discovery should be extended, and that at least some other scheduled dates should be altered. However, the parties have been unable to agree on an appropriate schedule to date. The parties' competing scheduling proposals are set forth and discussed in more detail below.

I. DISCOVERY DISPUTES

1) Lupin's Refusal to Provide Damages-Related Discovery

In this patent infringement suit, Shionogi has claimed damages as a result of Lupin's stealth, at-risk launch of infringing copies of Shionogi's FORTAMET® diabetes drug.

On September 30, 2011, Lupin flooded the U.S. market with its generic product. Shionogi moved for, and this Court granted, a preliminary injunction enjoining additional infringing sales by Lupin. On January 31, 2012, Shionogi filed an Amended Complaint, adding a claim for damages arising out of Lupin's patent infringement. D.I. 313. Lupin consented to that filing. After adding its damages claim, Shionogi served discovery requests on Lupin related to patent damages. Lupin has refused to provide the requested discovery. Accordingly, Shionogi asks the Court to compel Lupin to produce documents, answer to interrogatories, and provide Rule 30(b)(6) testimony related to Shionogi's claim for damages.

Lupin's position appears to be that Judge Kugler's October 20, 2011 ruling, issued during a telephone hearing concerning expedited discovery for the preliminary injunction proceeding, forecloses Shionogi's ability to obtain the requested discovery now that its damages case is proceeding on the merits.[1] Judge Kugler's ruling, however, was limited to Shionogi's need for the requested discovery for the purposes of the preliminary injunction only:

> I'm not convinced that the plaintiff needs this information ***in order to establish its irreparability argument in the motion for a preliminary injunction***. I think Rule 26 really has sort of a balancing concept in it. The information sought I don't think is terribly important to the plaintiffs to prove ***what they need to prove in the motion***. And it's incredibly harmful to the defendants if it somehow escapes from the confines of that Protective Order that

[1] During the injunction proceeding, Shionogi sought discovery regarding Lupin's infringing launch.

> we've been talking about. So I don't think it's really terribly relevant and I'm not going to order that Lupin comply with those discovery requests as to that sort of information.

October 20, 2011 Hearing Transcript ("Tr.") at 17:22-18:8 (emphasis added).

Accordingly, Lupin is incorrect that the requested discovery, highly relevant to the issue of Shionogi's damages, is foreclosed by Judge Kugler's prior ruling on the relevance of certain discovery to the determination of a preliminary injunction.[2]

a) The Requested Discovery

On February 7, 2012, Shionogi served a Rule 30(b)(6) notice on Lupin seeking, among other things, damages related testimony. *See* Ex. A (Notice of 30(b)(6) Deposition to Lupin) at Topics 8, 13-15, 19, 22, and 25-38 (collectively, "Damages Topics"). Lupin responded on March 22, 2012, stating that it would ***not*** produce a witness on those topics. *See* Ex. B (March 22, 2012 Ltr. from Lupin) at 2. Lupin's letter stated no objections to the deposition topics, other than its flat refusal to provide a witness on these topics. *See id.*

On February 14, 2012, Shionogi served document requests directed to its damages claim. *See* Ex. C at Request for Production Nos. 33-37, 40-45, 53 and 79 (collectively "Damages Requests," and collectively with Damages Topics and Shionogi's expedited interrogatories, dated October 4, 2011 (Ex. D), "requested damages discovery"). In particular, Shionogi seeks the following discovery relevant to its damages claim, including documents regarding the manufacture, importation, sale, offer for sale, or shipment by Lupin of its infringing product, including communications or agreements with third parties or customers regarding Lupin's at-risk launch. More specifically, Shionogi seeks documents and other written discovery sufficient to show:

- The sale of Lupin's infringing products, including documents concerning: (1) the identity of the parties to whom Lupin's products were shipped or sold; (2) the unit quantity of 500 mg and 1000 mg tablets that were shipped or sold to each party; (3) the price at which the 500 mg or 1000 mg tablets were sold or shipped to each party, including any discounts and rebates; (4) the costs to manufacture the products (i.e.,

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[2] Indeed, Lupin's main attack on the requested expedited discovery was that it was not relevant to the preliminary injunction proceeding. *See* D.I. 219 (October 18, 2012 letter) at 1 ("[T]he documents Shinogi [sic] seeks to compel are not relevant to the Court's consideration of a preliminary injunction . . . ."); D.I. 241 (October 20, 2011 letter) at 2 ("***The standard of relevance is considerably higher here than in normal discovery***, for two reasons. First, in the context of expedited discovery in connection with a preliminary injunction, the burden is on the party seeking discovery to 'narrowly tailor' its requests to seek only the information necessary to support preliminary relief.") (emphasis added); *id.* at 6 ("Shionogi cannot demonstrate relevance, because the requested information is not relevant to irreparable harm or the other preliminary injunction factors.").

raw material costs, administrative or overhead expenses, production costs, royalties paid, etc…); (5) the profits Lupin received for each such sale; (6) the date that Lupin's products were shipped or sold to each party; or (7) the reason why each party was selected for shipment or sale, among others. *See* Ex. C at Request for Production No. 41 and Ex. D at Expedited Interrogatory Nos. 1-2.

- Any analysis or study by Lupin of the actual or potential market for a generic version of Shionogi's drug, FORTAMET, and the impact on the market for FORTAMET® caused, or expected to be caused, by Lupin's ANDA product. *See* Ex. C at Request for Production No. 43.
- The research and development of Lupin's infringing products, including the identification of each person involved, and time spent and costs incurred in the research and development of Lupin's Extended Release Metformin Product. *Id.* at Request for Production Nos. 46-48.
- Lupin's forecasting, budgeting, and financial or strategic planning relating to the infringing products, including any evaluations of criteria of profitability, profit studies, return-on-investment analyses, or pricing guidelines and including sales, market, budget, cost, margin or revenue forecasts or projections, business plans, marketing plans or competitive analyses, among others. *Id.* at Request for Production No. 53.

Lupin refused to produce the requested damages related discovery on the basis that the discovery was allegedly foreclosed by Judge Kugler's October 20, 2011 ruling from the preliminary injunction proceedings. *See* Ex. E at Responses to Request for Production Nos. 33-37, 40-45, 53 and 79.

b) Shionogi's Requested Damages Discovery is Directly Relevant to Its Damages Claim

The scope of discovery under the Federal Rules of Civil Procedure is broad, and a court "may order discovery of ***any matter relevant to the subject matter involved in the action***." *See* FED. R. CIV. P. 26(b)(1) (emphasis added). As explained in the accompanying declaration of Christopher P. Gerardi, the requested discovery is generally accepted and usual and customary for evaluating a patent damages case, and ***highly relevant*** to multiple issues stemming from Shionogi's damages claim. *See* Ex. F (Declaration of Christopher P. Gerardi (hereinafter "Gerardi Dec.")) at ¶¶ 9-13. Indeed, during the preliminary injunction proceeding, Lupin's own economics experts stated that a more complete assessment of "[t]he availability of lost profits or reasonable royalty, the amount of damages potentially attributable to Lupin compared to other defendants, and other aspects of damages would be determined through damages discovery and expert discovery."[3]

[3] Declaration of Mark M. Gleason and Ivan T. Hoffman dated October 19, 2011, pages 13-14, footnote 21. Messrs. Gleason and Hoffman's opinion was not qualified or limited to discovery only of Shionogi's documents and information.

As explained by Mr. Gerardi, Shionogi will argue that it should be awarded the profits it lost as a result of Lupin's infringing sales. *See* Ex. F (Gerardi Dec.) at ¶ 14. For Shionogi to be awarded lost profits (including price erosion) as a measure of damages, it must be reasonably likely that Shionogi would have made Lupin's accused sales but for Lupin's act of infringement. Relevant lost profits damages-related information commonly sought by both parties through discovery includes, but is not limited to: (1) accused infringing sales and cost data on accused products, including gross sales, average selling prices, rebates, net sales, cost of raw materials and other incremental costs of the accused products, among others; (2) the accused infringer's documents and information related to customers who bought the accused products; (3) information on the nature of demand for the accused products; (4) market analyses identifying the competitors of the accused products and competitor sales; and (5) any additional information by which to determine if lost profits may be appropriate and the amount thereof. *Id.*

Shionogi expects—and Lupin has not denied—that Lupin will argue at trial that: (1) lost profits should not apply in this case; (2) if lost profits do not apply in this case, the appropriate measure of damages is a reasonable royalty; and (3) Lupin's sales may have "expanded" the market for FORTAMET®, and as to any sales above and beyond what Shionogi would have sold but for the infringing conduct, Shionogi is entitled only to a reasonable royalty.

Mr. Gerardi explains that the requested damages discovery is relevant to the type and amount of economic damages owed to Shionogi as a result of Lupin's at-risk launch and infringing sales. *Id.* at ¶ 9. The requested damages discovery is relevant for determining whether or not lost profits are an appropriate means for making Shionogi whole. *Id.* at ¶ 14. Alternatively, were a reasonable royalty analysis to apply, then the requested damages discovery would be relevant in calculating the appropriate royalty base and royalty rate that would have resulted from a hypothetical negotiation between Shionogi and Lupin.[4] *Id.* at ¶ 15.

c) **Lupin Cannot Demonstrate Good Cause to Prevent Production of its Sales Information**

Lupin also argues that the requested damages discovery should be denied because it is allegedly "commercially sensitive." However, a protective order is in place to govern the production of confidential and highly confidential information, which expressly includes "competitively sensitive information." *See* D.I. 76 at Section I., ¶ B. Moreover, federal litigation "invariably involves" discovery of some confidential information, and the confidential

[4] Shionogi notes that the requested damages discovery is also relevant to the issue of commercial success and therefore, to non-obviousness of the patents-in-suit. *Sanofi-Aventis Deutschland GMGH, v. Glanmark Pharm. Inc.*, -- F. Supp. 2d --, 2011 WL 4594205, at *6 (D.N.J. Sept. 30, 2011). The requested damages discovery is further relevant to Shionogi's willful infringement claim, to the extent it demonstrates that Lupin had a significant financial interest in willfully infringing the patents-in-suit. *Amsted Indus. Inc. v. Nat'l Castings, Inc.*, No. 88 C 0924, 1989 WL 68393, at *1 (N.D. Ill. June 15, 1989).

nature of information alone is not enough to shield it from discovery. *JAB Distributors, LLC v. London Luxury, LLC*, No. 09-cv-5831, 2010 WL 4008193, at *3 (N.D. Ill. Oct. 13, 2010). While courts may afford some limited protection for extremely sensitive confidential or trade secret information, the ***party seeking the protection must show "good cause"*** that the information should not be revealed, and that there is a ***clearly defined and serious injury*** that would result from such dissemination. FED. R. CIV. P. 26(c)(7) (emphasis added); *see also Moore U.S.A., Inc. v. Standard Register Co.*, No. 98-485C(F), 2000 WL 876884, at *7 (W.D.N.Y. May 26, 2000).

Financial and customer information, of the exact types sought here, are routinely produced pursuant to a protective order in a patent infringement litigation. *See* Gerardi Dec. at ¶ 12. There is nothing unique about this case that would warrant treating Lupin any differently from any other patent infringement defendant from whom patent damages are sought.

Lupin also cannot show good cause to preclude production of the otherwise relevant damages discovery. Lupin seeks to benefit financially from its stealth launch while, at the same time, asks this Court to shield it from discovery by arguing that these infringing sales were commercially sensitive. Lupin cannot have it both ways, and it would be fundamentally unfair to deprive Shionogi of the discovery it seeks relating to Lupin's infringing activities. Indeed, any alleged "hardship" Lupin now faces as a result of its at-risk launch is of its own making. Accordingly, Lupin cannot show good cause to preclude production of the damages discovery.[5]

d) Lupin Will Not Be Harmed by Production of Relevant Damages Documents

Lupin previously argued that it would be "harmed" if its damages related documents were produced. *See* D.I. 241 at pp. 2, 5. But the cases on which Lupin relies do not support its position. As an initial matter, a majority of these cases relate to expedited discovery in the context of a preliminary injunction. The rationale applied by the courts in those cases is inapplicable here. Lupin relies on two cases outside the preliminary injunction context, but both are readily distinguishable from this case. *Id.* at 2. For example, in *RyCON Specialty Foods*, the court found that the requested sales information had "no relevance to the crucial threshold issue" in the case, and denied the defendant's motion to compel disclosure of competitively sensitive information because its requests were based on a "thinly supported and speculative" underlying claim. *RyCON Specialty Foods, Inc. v. Wellshire Farms, Inc.*, 2011 WL 1342998, at *8 (M.D. Pa. Apr. 7, 2011). In this case, the requested discovery is highly relevant to its damages claim and is typical of the information sought in patent damages cases. *See* Gerardi Dec. at ¶¶ 9-10.

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[5] Even if Lupin could show good cause to exclude the requested damages discovery, which it cannot, that would still not be enough for this Court to preclude its production. As Mr. Gerardi has explained, this discovery is relevant and necessary to Shionogi's damages claim (*see* Gerardi Dec. at ¶¶ 9-10), which is sufficient to rebut any good cause allegation made by Lupin. *Chembio Diagnostic Sys., Inc. v. Saliva Diagnostic Sys., Inc.*, 236 F.R.D. 129, 136 (E.D.N.Y. 2006).

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In *American Standard*, because there was no protective order of record, the court could not "determine whether disclosure would be restricted to counsel" and as a result, refused to compel production. *Am. Standard Inc. v. Pfizer Inc.*, 828 F.2d 734, 741 (Fed. Cir. 1987). This is not the case here. A two-tiered Protective Order (D.I. 76) is in place, permitting parties to produce information with the designation of "HIGHLY CONFIDENTIAL – OUTSIDE COUNSEL EYES ONLY." *Id.* at Section I., ¶ B. This Protective Order squarely addresses any of Lupin's concerns regarding confidentiality. Indeed, Lupin has not (and cannot) provide any explanation as to how the Protective Order in this case would fail to protect any allegedly sensitive damages related discovery. *L.G. Philips LCD Co. v. Tatung Co.*, 2007 WL 869700, at *3 (E.D. Ca. Mar. 21, 2007). Thus there is no basis to preclude production of the requested damages discovery on account that it may contain confidential information.

Finally, Shionogi has served third-party subpoenas to DDN/Obergfel LLC ("DDN") and Mr. Steven Schommer, both Lupin's agents for the at-risk launch. Lupin moved to quash those subpoenas in Illinois and Tennessee, arguing that the information sought was allegedly commercially sensitive, irrelevant, and that the discovery was precluded by Judge Kugler's October 20, 2011 ruling. Lupin has agreed to hold its motions to quash in abeyance until after the Court resolves the pending discovery disputes.

Accordingly, Shionogi requests the Court enter an order compelling Lupin to produce the requested damages related discovery, including production of documents responsive to Requests for Production Nos. 33-37, 40-45, 53 and 79 (Ex. C), responses to Shionogi's Expedited Interrogatories (Ex. D), and corporate testimony relating to Topics 8, 13-15, 19, 22, and 25-38 from Shionogi's Request for Rule 30(b)(6) Testimony (Ex. A).

2) Lupin's Responses to Other Shionogi Document Requests

Notwithstanding the parties' good faith efforts to resolve the issues during the Meet and Confers, Lupin has failed to provide adequate responses to certain of Shionogi's other requests for production.

a) Request for Production No. 39: Negotiations or Discussions with Sandoz

Shionogi sought all documents and things concerning [redacted] Shionogi subsequently served Request for Production No. 39 seeking related documents, to which Lupin responded "[t]here are no additional documents responsive to this request." [redacted]

Lupin subsequently changed its position, stating during the parties' Meet-and-Confer that this document should not have been produced, [redacted] Lupin also claimed that documents responsive to this request were irrelevant.

To the extent Lupin invokes Fed. R. Evid. 408, that rule does not apply to discovery, only to admissibility. *See Wyeth v. Orgenus Pharma*, Civ. No. 09-3235 (FLW), 2010 U.S. Dist. LEXIS 111004, at *11 (D.N.J. Oct. 19, 2010) ("The Court also finds that the license agreements and settlement agreements may lead to the discovery of admissible evidence on the question of the damages Plaintiff might sustain in the event Defendants were to launch a generic version of [plaintiff's drug]."). [redacted] Even if they were, Rule 408 permits the introduction into evidence of settlement documents other than for proof of liability. Here, the documents would not be used to prove liability, but may be relevant to Shionogi's damages claim, as well as its claim for willful infringement. [redacted]

The Court should order Lupin to produce all documents responsive to this request and all documents [redacted]

b) Request for Production Nos. 46, 47, and 48: Research and Development

Request for Production Nos. 46-48 concern information about the research and development leading to Lupin's infringing product. The requests seek, among other things, documents identifying each person involved in that effort and his or her role, including documents concerning development efforts that did not result in the filing of an ANDA or did not prove to be bioequivalent to FORTAMET®. *See* Ex. C at Request for Production Nos. 46-48. Lupin responded to these requests by directing Shionogi to previous objections and to "documents already produced."

Lupin's production is deficient. Prior to the Meet-and-Confer, [redacted] At the Meet-and-Confer, Lupin again asserted that its production with respect to these requests was complete, and that it would provide

Shionogi with Bates numbers identifying the remaining responsive documents. Lupin has not yet done so.

Lupin's production appears to be incomplete and Shionogi requests that the Court order Lupin to produce all documents responsive to these requests, including all documents [redacted] *See* Ex. C at Request for Production No. 46.

Lupin also has refused to produce document [redacted] Lupin's refusal to produce the requested documents is improper. To understand Lupin's design process as a whole, Shionogi must have access not only to testing on formulations that succeeded, but also those that were considered but failed. For example, these requested documents may show that Lupin chose to copy the patented invention because it could not get other formulations to work.

Shionogi requests that the Court enter an Order compelling Lupin to produce all documents concerning the research and development of not only its ANDA product, but also any extended release metformin product that Lupin did not submit in an ANDA (*see* Ex. C at Request for Production No. 47) or that did not show bioequivalence to FORTAMET® (*see id.* at Request for Production No. 48).

c) Requests for Production No. 50: Lupin's Decision to File its ANDA

Request for Production No. 50 seeks documents concerning Lupin's decision to file its ANDA. *See* Ex. C at Request for Production No. 50. Lupin has asserted that it "has no additional discoverable documents." *See* Ex. E at Response to Request for Production No. 50. At the Meet-and-Confer, Lupin stated that all responsive documents had been produced, but that it would double check its production for completeness and report back to Shionogi. Lupin has not yet done so. Lupin's production to date contains little, if any, evidence of the decision process leading to the filing of Lupin's ANDA, and there are virtually no emails on this subject. In fact, the vast majority of Lupin's emails are dated after 2007, after the decision to file had already been made.

Shionogi requests that the Court order Lupin to produce all documents responsive to this request, and specifically to expand its search to the years 2004-2006, and to custodians involved in the deliberative process concerning the filing of the ANDA, to capture the appropriate documents and communications.

d) Request for Production Nos. 56, 59, 62, and 63: Study 213-09 and Ashco

One of the central issues in this litigation is Lupin's assertion that "Study 213-09" demonstrates that its generic product does not infringe the '866 patent in suit. Lupin conducted this study after this litigation began, and it was never submitted to the FDA. Ashco Contract

Research Centre ("Ashco") conducted the study on Lupin's behalf. During the preliminary injunction proceeding, Shionogi submitted expert reports from Dr. Fleckenstein providing his opinion that Study 213-09 was scientifically unreliable for a host of reasons. *See* D.I. 210 at ¶¶ 55-69. In partial response, Lupin submitted a declaration from Ashco's Dr. Batheja, attempting to counter some of the flaws identified by Dr. Fleckenstein. *See* D.I. 232 at ¶¶ 3-15.

i. Request for Production No. 56

Request for Production No. 56 seeks a variety of details concerning Study 213-09. *See* Ex. C at Request for Production No. 56. In response, Lupin claimed that any responsive documents were either protected by privilege or had already been produced. *See* Ex. E at Response to Request for Production No. 56. At the Meet-and-Confer, Lupin reaffirmed these positions, but offered to double check its production and report back to Shionogi, providing Bates numbers of responsive documents.[6] Lupin has not yet done so, and Shionogi believes Lupin's production is incomplete. For example, Lupin has not produced its communications or contract with Ashco concerning the study. Accordingly, Shionogi requests the Court order Lupin to immediately identify all documents that it has already produced relating to Study 213-09, and to produce any responsive documents not already produced.

Further, by relying on litigation-inspired Study 213-09 as supposed evidence of non-infringement, Lupin has waived any associated work product immunity. *See*, *e.g.*, D.I. 230 (Lupin's opposition P.I. brief) at 13. Therefore, Lupin should be ordered to produce all documents relating to Study 213-09 previously withheld on the ground of work product immunity, including communications between Lupin, its counsel and/or Ashco concerning that study.

ii. Request for Production No. 59

Request for Production No. 59 seeks documents in the possession, custody or control of Ashco relating to Study 213-09. *See* Ex. C at Request for Production No. 59. Lupin has asserted that it has no responsive documents in its possession, custody, or control, but that it will "ask" Ashco if it possesses responsive documents and if it is willing to produce them. Shionogi believes that Lupin does, in fact, have possession, custody, or control over documents relating to a study performed for it. Indeed, the fact that Lupin was able to obtain a declaration from Mr. Batheja, the management representative at Ashco responsible for Study 213-09, demonstrates that it has such control. D.I. 232. Moreover, as the party in possession of its own communications with Ashco, including documents concerning any contractual relationship

[6] At the Meet-and-Confer Lupin noted that it had agreed to produce documents concerning batch records for Study 213-09 in response to Request for Production No. 38 ("All batch records for the manufacture of Lupin's ANDA Metformin Products"). Lupin's agreement to produce batch records, while welcome, only confirms that Lupin has not in fact produced all documents responsive to Request for Production No. 56, and relates to only one of eleven categories of documents contained in Request 56.

between it and Ashco, Lupin should not be permitted to hide behind facts in its sole possession and, nonetheless assert that it has no control, when those documents may, in fact, evidence precisely the opposite. Accordingly, the Court should order Lupin to obtain and produce all documents responsive to this request.

iii. Request for Production Nos. 62, 63

Request for Production Nos. 62 and 63 seek information sufficient to identify all clinical trials, bioequivalence studies, or other testing that Ashco performed for Lupin, and those that were actually submitted to the FDA. *See* Ex. C at Request for Production Nos. 62, 63. Lupin has asserted that no responsive documents exist. Accordingly, Shionogi asked for confirmation that [redacted]. Lupin refused to provide that confirmation, stating that whether that fact was true or not is irrelevant. The reliability of Study 213-09, and the possible bias of Ashco, are relevant to this case, for example, to demonstrate that Lupin [redacted]

Accordingly, Shionogi requests the Court order Lupin to either admit that this was the [redacted], or to produce the requested discovery.

3) Mylan's Responses to Interrogatory Requests to Identify Persons

Interrogatory Nos. 3-9 to Mylan seek the identity of persons with knowledge regarding research and development, manufacture, testing and analysis of Mylan's ANDA product, as well as Mylan's preparation of its ANDA and Notice Letter. *See* Ex. H at Interrogatory Nos. 3-9. Mylan objected, *inter alia*, that the interrogatories were unduly burdensome and "designed to harass and oppress" for seeking the identification of all natural persons. Instead, Mylan identified only the corporate entities, Mylan and Matrix Laboratories Ltd., as individuals with knowledge, and referenced their initial disclosures as "likely" to also contain responsive information. *See* Ex. I at Response to Interrogatory Nos. 3-9.

In a January 25, 2011 letter (D.I. 95), Shionogi represented to the Court that there was no longer a dispute regarding Mylan's failure to identify persons in response to Interrogatory Nos. 3-9 on the basis of Mylan's representation that "it will ***investigate whether there are other individuals who should be identified*** as having substantial knowledge, and ***supplement the subject interrogatories accordingly***." D.I. 95 at 2 (emphasis added). Mylan now claims that based on Shionogi's January 25, 2011 letter, Mylan's response to Interrogatory Nos. 3-9 is sufficient. But Shionogi never withdraw its objection to Mylan's refusal to identify knowledgeable persons in its interrogatory responses. Mylan has now refused to supplement its responses to Interrogatory Nos. 3-9, insisting they have met their obligation to respond fully by referencing their initial disclosures.

Shionogi requests that Mylan verify that there are no additional persons that have substantive knowledge of the subjects identified in Interrogatory Nos. 3-9 and specify which of

the individuals from the initial disclosures have knowledge responsive to each of those interrogatories. *See, e.g.*, *Davis v. Springfield*, Nos. 04-3168, 07-3096, 2009 WL 268893, at *5 (C.D. Ill. Jan. 30, 2009) ("Defendant may not cite generally to its Initial Disclosures, but must supplement its response to specifically identify which witnesses listed in its Initial Disclosures are responsive to [plaintiff's interrogatory].")

4) Current Disputes Regarding Depositions

a. Location of Depositions

Shionogi has requested depositions of Lupin and Mylan personnel who reside in India. Lupin has indicated that three of the four requested witnesses who reside in India are available to come to the United States for their depositions, but that the fourth is not. Shionogi advised Lupin that it would hold its request for the fourth person in abeyance, and asked that Lupin confirm that the three witnesses would be made available for deposition in the United States. Lupin has not yet done so. Mylan has indicated its willingness to bring three witnesses identified in its Initial Disclosures to the United States for deposition, but has not yet confirmed that those witnesses will, in fact, travel to the United States.

b. Depositions of Chief Executive Officers

Lupin has also refused, after initially agreeing to provide dates for all requested witnesses, to make its U.S. CEO, Vinita Gupta available for deposition, demanding an explanation of her relevance. Ms. Gupta was the person responsible for launching Lupin's ANDA Product at-risk, and thus her testimony may be relevant to the issues of damages and willful infringement. Accordingly, Shionogi requests that the Court order Lupin to make Ms. Gupta available for deposition.

Lupin, in turn, requested the deposition of Shionogi's CEO, Dr. Keller. Lupin asserted that his deposition is relevant to Shionogi's claim that it would be irreparably harmed during the preliminary injunction proceeding. However, Dr. Keller does *not* have unique knowledge that could not be provided by other employees, and the issue of irreparable harm has now been decided. Accordingly, there appears to be no legitimate reason, other than harassment, for Dr. Keller's deposition. *See Ford Motor Co. v. Edgewood Props.*, Civ. No. 06-1278, 2011 U.S. Dist. LEXIS 67227, at *11-13 (D.N.J. 2011) (affirming grant of protective order excusing CEO and other executives from depositions where they did not possess "unique knowledge" and where information could be obtained from lower level employees).

Lupin also has requested the deposition of Dr. Isao Teshiroghi, the CEO of Shionogi & Co. Ltd., the parent of the Shionogi U.S. entity that is a party to this case. Dr. Teshiroghi resides in Japan. As with Dr. Keller, Lupin asserts that, because Shionogi referenced its relationship with its Japanese parent during the preliminary injunction proceedings, Dr. Teshiroghi's deposition is somehow relevant. Shionogi & Co. Ltd. is not a party to this litigation and Dr. Teshiroghi has no personal knowledge of the facts and circumstances of the case, particularly those that cannot be obtained through other discovery. *See Advanced Micro Devices, Inc. v. Intel*

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Corp. (In re Intel Corp. Microprocessor Antitrust Litig.), 2008 U.S. Dist. LEXIS 103019 (D. Del. 2008) (ordering issuing party to "minimize the burden" on non-party executives).

Therefore, Shionogi asks that the Court enter a protective order holding that the depositions of Dr. Teshiroghi and Dr. Keller should not proceed.

II. AMENDED SCHEDULE

All parties agree that fact discovery cannot be completed by April 16, 2012. However, Lupin and Shionogi disagree as to the appropriate schedule going forward. Below is a chart comparing the dates in the current Amended Scheduling Order to both Lupin's and Shionogi's proposals:

Deadline	Current Amended Scheduling Order	Shionogi's Proposal	Lupin's Proposal
Pretrial fact discovery	April 16, 2012	July 13, 2012	May 25, 2012
Opening expert reports	June 18, 2012	August 24, 2012	June 18, 2012
Rebuttal expert reports	June 30, 2012	September 28, 2012	June 30, 2012
Expert depositions	August 10, 2012	November 2, 2012	August 10, 2012
Dispositive and Daubert motions	September 10, 2012	November 16, 2012	September 10, 2012

Lupin's proposed schedule is unrealistic. The parties will require time to substantially complete document production, particularly on Shionogi's damages claim. Indeed, no merits depositions have taken place. Plaintiffs have notified Defendants of their intent to take approximately twenty fact depositions in total, as well as Rule 30(b)(6) depositions of both Lupin and Mylan. Shionogi believes that Defendants will take a similar number of depositions. Lupin's proposed schedule would require the parties to conduct approximately forty depositions in seven weeks (which would include the depositions Lupin now seeks to occur in India). Shionogi submits that its proposed schedule, with which Andrx concurs, is much more realistic.

Although Lupin will likely argue that it requires an expedited discovery schedule because it is currently enjoined, that was the risk Lupin took in undertaking an at-risk launch. Furthermore, the Federal Circuit has scheduled oral argument on Lupin's appeal of the injunction for April 18, 2012. *See* Order dated March 28, 2012, *Sciele Pharma Inc. v. Lupin Ltd.*, No. 2012-1228 (Fed. Cir.). If the Federal Circuit reverses or vacates the injunction grant, it will be lifted; if affirmed, there is no need to compress the schedule. Either way, the injunction will not have an impact on the case schedule.

III. MYLAN 30-MONTH STAY EXPIRATION

By virtue of the Hatch-Waxman statute, the filing of this lawsuit against Mylan resulted in an automatic 30-month stay of FDA approval for Mylan's ANDA. [redacted]

Original Filing Date: April 2, 2012
Redacted Filing Date: May 9, 2012

[redacted]. Accordingly, Shionogi has asked Mylan to provide Plaintiffs with 60 days notice prior to launching a commercial product, to provide adequate time to file a preliminary injunction motion. Mylan is considering this request. Should Mylan not agree to provide adequate notice for Shionogi to seek and obtain a preliminary injunction prior to [redacted] Shionogi will request that the Court set a briefing schedule.

Shionogi appreciates Your Honor's consideration of these issues and looks forward to the hearing on April 5.

Respectfully,

/s/ Karen Jacobs Louden

Karen Jacobs Louden (#2881)

KJL/lm
5841629.1
cc: Clerk of the Court (by e-filing)
All Counsel of Record (by e-mail)

Original Filing Date: April 2, 2012
Redacted Filing Date: May 9, 2012